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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,987

Applicant(s)

BURBANK ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,49,52-61,65,67-76 and 78-95 is/are pending in the application.
- 4a) Of the above claim(s) 93-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,49,52-61,65,67-76 and 78-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on September 7, 2004 and September 24, 2004 have been entered.

The Examiner acknowledges the amendments to claims 1, 49-61, 65, 67, 68, 70-76 and 78; the cancellation of claims 62-64, 66 and 77; and the addition of new claims 93-95. Claims 1, 49, 52-61, 65, 67-76 and 78-95 are pending.

Election/Restrictions

2. Newly submitted claims 93-95 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 93-95 appear to be directed to a separate species of the apparatus and method of the originally presented claims that has not previously been presented. Regarding claim 93, the claimed "assembly" includes a shaft and a localization device that appears to be equivalent to the fixation element of the originally presented claims; however, claim 93 additionally recites a tissue separation element that has a distal part that is movable between a retracted state and an axially extending state. This feature does not appear to be equivalent to the radially expandable side-cutting element of the originally presented claims that do not appear to have such a distal part. Furthermore, the specification lacks

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proper antecedent basis for this claim terminology used in the new claims, which raises potential new matter issues. Regarding claim 94 and 95, the claimed "method" includes method steps of "separating a tissue section" and "encapsulating the separated tissue section to effectively capture the separated tissue section" that are not required by the originally presented claims. The specification lacks proper antecedent basis for this claim terminology used in the new claims, particularly regarding any encapsulation of tissue, which raises potential new matter issues.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 93-95 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

3. Claim 52 is objected to because of the following informalities: in line 2, --at least one-- apparently should be inserted before "fixation". Appropriate correction is required.
4. Claim 54 is objected to because of the following informalities: in line 2, "which" apparently should read --elements--. Appropriate correction is required.
5. Claim 65 is objected to because of the following informalities:
 - a. In line 1, --a-- apparently should be inserted following "from".
 - b. In line 6, "dista" apparently should read --distal--.

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c. In line 14, --of--, --from-- or --at-- apparently should be inserted following "specimen".

Appropriate correction is required.

6. Claim 67 is objected to because of the following informalities: in line 2, "from a" (second occurrence) apparently should be deleted. Appropriate correction is required.

7. Claim 68 is objected to because of the following informalities: in line 10, "desired" apparently should be deleted. Appropriate correction is required.

8. Claim 73 is objected to because of the following informalities: in line 10, "the target" apparently should read --target--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 55-57 and 78-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 recites the limitation "the target site" in lines 7 and 10-12. There is insufficient antecedent basis for this limitation in the claim. There is no "target site" recited in the claims prior to these recitations.

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Regarding claim 78, the claim is indefinite because the claim is dependent on canceled claim 77.

Claim 78 recites the limitation "the distal shaft portion" in lines 1-2 and 3-4. There is insufficient antecedent basis for this limitation in the claim. There is a shaft distal end, but no distal shaft portion is recited in claims prior to this recitation.

Regarding claim 79, the claim is indefinite because the claim language is unclear as to whether the limitation "which is disposed on said distal end proximal of said distal tip and which is configured for securing the distal end..." recited at lines 7-9 is intended to refer to the "fixation element" or the "free end".

Regarding claim 85, the claim is indefinite because the claim language is unclear as to whether the limitation "which is spaced proximal to the distal tip and which is configured for engaging tissue" recited at lines 5-6 is intended to refer to the "fixation element" or the "free end".

Claim 91 recites the limitation "said placing step" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no "placing step" recited in the claims prior to this recitation.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 52-60, 65 and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Krag ('940).

The present application is a continuation of U.S. Serial No. 09/146,185 which is a continuation-in-part of U.S. Serial No. 09/057,303 which claims priority to U.S.

Provisional Application No. 60/076,973. U.S. Serial No. 09/057,303 fails to disclose a medical device including at least one fixation element which has a free end configured to secure a distal shaft portion to tissue and an opposite end secured to the distal shaft portion. Such a feature is not disclosed until U.S. Serial No. 09/146,185. Therefore, the earliest effective filing date to which the present application may claim priority is the September 1, 1998 filing date of U.S. Serial No. 09/146,185.

Krag teaches a medical device and method for bracketing and removing tissue. The device **300** includes an elongated shaft **320** having a distal shaft portion with a distal tip **326** and a proximal shaft portion **304**. The distal shaft portion is configured for placement in a patient's body at a target site. The distal tip **326** includes a tissue penetrating or cutting element. A plurality of fixation elements **310** are provided, each having a free end **312** configured to secure the distal shaft portion within tissue at the target site and an opposite end secured to the distal shaft portion at a location proximal to the distal tip. The fixation elements move between a radially retracted position (Fig. 12) for delivery and a radially extended configuration (Fig. 13) for deploying the free end into tissue. In operation, the distal tip is advanced through body tissue until the distal

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shaft portion is placed adjacent to a target tissue site, the fixation elements are radially extended so that the distal shaft portion becomes secured adjacent to the target tissue; and a tissue specimen is acquired from the target site.

13. Claims 1, 49 and 52-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al. ('384). Gough et al. teaches a medical device and method for anchoring and later ablating tissue. The device **10** includes an elongated shaft **18** having a distal shaft portion with a distal tip and a proximal shaft portion. The distal shaft portion is configured for placement in a patient's body at a target site. The distal tip includes a tissue penetrating or cutting element **14**. At least one fixation element **16** is provided for anchoring tissue, each having a free end configured to secure the distal shaft portion within tissue at the target site and an opposite end secured to the distal shaft portion at a location proximal to the distal tip. The device includes a plurality of fixation elements in certain embodiments. The fixation elements move between a radially retracted position for delivery and a radially extended configuration for deploying the free end into tissue. The tissue penetrating elements and the fixation elements are electrosurgical elements. In operation, the distal tip is advanced through body tissue until the distal shaft portion is placed adjacent to a target tissue site and the fixation elements are radially extended so that the distal shaft portion becomes secured adjacent to the target tissue.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 49, 52-61, 65, 67 and 92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 13, 14, 18, 19, 28, 36, 38 and 42 of U.S. Patent No. 6,312,429. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claims of the present application recite medical devices having essentially the same structural elements and methods having essentially the same method steps. The claims differ primarily in the terminology used to refer to similar structural elements and method steps. Additionally, the claims of the patent recite additional structural elements and method steps that are not required by claims of the present invention. Since the claims of the patent "anticipate" the broader claims of the present application, the claims are not patentably distinct.

16. Claims 1, 49, 52-61, 65 and 67-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 6 and 9-11 of U.S. Patent No. 6,540,693. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and

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the claims of the present application recite medical devices having essentially the same structural elements and methods having essentially the same method steps. The claims differ primarily in the terminology used to refer to similar structural elements and method steps. Additionally, the claims of the patent recite additional structural elements and method steps that are not required by claims of the present invention. Since the claims of the patent "anticipate" the broader claims of the present application, the claims are not patentably distinct.

17. Claims 1, 49, 52-61, 65 and 67-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 9, 14, 27 and 29 of U.S. Patent No. 6,540,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claims of the present application recite medical devices having essentially the same structural elements and methods having essentially the same method steps. The claims differ primarily in the terminology used to refer to similar structural elements and method steps. Additionally, the claims of the patent recite additional structural elements and method steps that are not required by claims of the present invention. Since the claims of the patent "anticipate" the broader claims of the present application, the claims are not patentably distinct.

18. Claims 1, 49, 52-61, 65 and 67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 9 of U.S. Patent No. 6,638,234. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because both the claims of the patent and the claims of the present application recite methods having essentially the same method steps. The method of the patent also requires a medical device having similar structural limitations as the medical devices claimed in the present application. The claims differ primarily in the terminology used to refer to similar structural elements and method steps.

Additionally, the claims of the patent recite additional structural elements and method steps that are not required by claims of the present invention. Since the claims of the patent "anticipate" the broader claims of the present application and the methods of the patent require a medical device having essentially the same structure as the claimed medical devices of the present application, the claims are not patentably distinct.

19. Claims 1, 49 and 52-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 13-20 and 25 of U.S. Patent No. 6,679,851. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claims of the present application recite medical devices having essentially the same structural elements. The device of the patent also requires a method having similar method steps to the claims of the present application in order to function properly. The claims differ primarily in the terminology used to refer to similar structural elements. Additionally, the claims of the patent recite additional structural elements that are not required by claims of the present invention. Since the claims of the patent "anticipate" the broader claims of the present application, and the medical devices of the patent claims require methods having method steps substantially the same as those required by the

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claims of the present application in order to function properly, the claims are not patentably distinct.

20. Claims 1, 49 and 52-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,716,179. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claims of the present application recite medical devices having essentially the same structural elements. The device of the patent also requires a method having similar method steps to the claims of the present application in order to function properly. The claims differ primarily in the terminology used to refer to similar structural elements. Additionally, the claims of the patent recite additional structural elements that are not required by claims of the present invention. Since the claims of the patent "anticipate" the broader claims of the present application, and the medical devices of the patent claims require methods having method steps substantially the same as those required by the claims of the present application in order to function properly, the claims are not patentably distinct.

21. Claims 1 and 52-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 18 and 19 of copending Application No. 2002/0068879. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the co-pending application and the claims of the present application recite medical devices

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having essentially the same structural elements. The device of the co-pending application also requires a method having similar method steps to the claims of the present application in order to function properly. The claims differ primarily in the terminology used to refer to similar structural elements. Additionally, the claims of the co-pending application recite additional structural elements that are not required by claims of the present invention. Since the claims of the co-pending application "anticipate" the broader claims of the present application, and the medical devices of the co-pending application claims require methods having method steps substantially the same as those required by the claims of the present application in order to function properly, the claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1, 49, 52-61, 65, 67 and 92 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 10, 15, 16, 20 and 21 of copending Application No. 2002/0077628. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the co-pending application and the claims of the present application recite medical devices having essentially the same structural elements and methods having essentially the same method steps. The claims differ primarily in the terminology used to refer to similar structural elements and method steps. Additionally, the claims of the co-pending application recite additional structural elements and method steps that are not required by claims of the present invention. Since the claims of the co-

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pending application "anticipate" the broader claims of the present application, the claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1, 49, 52-61, 65 and 67-91 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 9 and 25-27 of copending Application No. 2003/0144605. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the co-pending application and the claims of the present application recite medical devices having essentially the same structural elements and methods having essentially the same method steps. The claims differ primarily in the terminology used to refer to similar structural elements and method steps. Additionally, the claims of the co-pending application recite additional structural elements and method steps that are not required by claims of the present invention. Since the claims of the co-pending application "anticipate" the broader claims of the present application, the claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

24. Applicant's arguments, see page 12 of the Remarks filed September 7, 2004, with respect to the rejection of claims 1, 52, 55, 58 and 65 under 35 U.S.C. 102(b) as being

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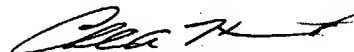
anticipated by Ghiatas (U.S. Pat. No. 5,158,084) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new grounds of rejection are made in view of Krag ('940) and Gough et al. ('348) for the reasons discussed hereinabove.

Conclusion

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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September 28, 2004